

I. Scientific Abstract

This is a phase I trial to evaluate DNA vaccination in patients with metastatic melanoma. The objective of this study is to determine the safety and immunogenicity of vaccination with the gene coding for mouse gp75 in patients with AJCC stage III and IV melanoma. We will assess whether DNA vaccination is safe and generates an immune response to an otherwise poorly immunogenic melanoma differentiation antigen.

The hypothesis that xenogeneic DNA encoding a homologous antigen is a potent vaccine will be tested. Studies in animal models have demonstrated that xenogeneic DNA (i.e., homologous DNA from a different species) can be more potent in inducing antibody and T cell responses against melanoma differentiation antigens than vaccination with self DNA. Patients will be vaccinated with xenogeneic (mouse) gp75 DNA delivered intramuscularly at four different dose levels (100, 500, 2000 or 4000µg) every three weeks for five immunizations. If patients have stable or clinically responding disease, additional vaccinations are administered every three months for up to three additional vaccinations. A total of at least 24 patients are planned. Patients' sera will be collected in order to measure the antibody response induced by the vaccine. Specifically, titers of IgM and IgG antibodies against mouse gp75 will be measured for serological response.